Medicare Allows Add-On Payments to Hospitals for Some New Products

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For the past few years, the controversy over expensive new pharmaceuticals has involved concerns over the cost of and access to cancer drugs, hepatitis C regimens, and other therapies in an outpatient setting, and whether insurers and programs such as Medicaid could afford to provide what in many cases are true advancements to the patients who need them. In the case of Medicare, therapies provided on an outpatient basis are reimbursed by Part B or D (mostly B) because the drugs are predominantly infused.

Access to expensive new drugs for patients who are in hospital beds, however, has been a much less visible issue given that the costs of those drugs are bundled into diagnosis-related groups (DRGs) and reimbursed as part of the global payment to a hospital in Part A Medicare.

But Part A drug payments are an issue, too, for both hospitals that balk at providing expensive new drugs to inpatients and for drug companies that see less hospital uptake of those drugs. To promote uptake, since 2000, the Medicare program has approved what are called technology add-on payments for expensive new drugs and medical devices in Part A for two or three years.

But the approval process is extremely complicated. This past spring, pharmaceutical companies and their lobby, the Pharmaceutical Research and Manufacturers of America (PhRMA), pressed the Centers for Medicare and Medicaid Services (CMS) to ease the standards it uses to determine if a new drug qualifies for technology add-on payments. Drug companies must apply for these add-on payments, which typically equal either less than 50% of the estimated costs of the new technology or medical service or less than 50% of the difference between the full DRG payment and the hospital's estimated cost for the case.

The CMS received nine applications for new technology add-on payments for fiscal year 2018, three of which were withdrawn before the proposed rule was issued. Of the remaining six applications, the CMS expressed varying concerns about each of them as to whether they met the three criteria necessary for a drug to be awarded an additional payment. The six applications were for: Edwards Intuity Elite valve system/LivaNova Perceval valve; Janssen's Stelara (ustekinumab); Kite Pharma's KTE-C19 (axicabtagene ciloleucel); Merck's Zinplava (bezlotoxumab); Celator Pharmaceuticals' Vyxeos (cytarabine and daunorubicin); and Isoray Medical/GammaTile, LLC's GammaTile.

In order for Medicare to approve add-on payments, a drug, medical service, or technology must meet three criteria. It must: 1) be new; 2) be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and 3) demonstrate a substantial clinical improvement over existing services or technologies.

The CMS does not consider a technology to be "new" if it is "substantially similar" to one or more existing technologies. The agency considers a technology substantially similar to an existing technology if it: 1) uses the "same or similar" mechanism of action; 2) is assigned to the same Medicare Severity DRG; and 3) treats the "same or similar" type of disease and the "same or similar" patient population.

Comments submitted by PhRMA contesting the application of these three criteria in the CMS's proposed calendar year 2018 determinations argued the use of the "substantially similar" test is overly restrictive and could prevent beneficiaries from accessing novel treatments. Its comments stated: "PhRMA is concerned that, in establishing this standard, CMS may be inappropriately restricting consideration of new products—especially as this 'substantial similarity' analysis now dominates CMS' discussion of virtually all the candidates for new technology payments."

The complaints of PhRMA and additional evidence submitted by Janssen Scientific Affairs resulted in the CMS backing away from its initial decision that ustekinumab, a biologic prescribed for the treatment of Crohn's disease, failed the "substantially similar" test. The CMS argued ustekinumab has the same mechanism of action as other cytokine-selective monoclonal antibodies used to treat Crohn's disease. Janssen replied that a critical differentiator is that ustekinumab has a mechanism of action that sets it apart from other available biologic products. There are no other products on the market that specifically target the cytokines interleukin (IL)-12 and IL-23. It has become clear that while many patients respond to tumor necrosis factor (TNF) inhibition, 20% to 25% will not respond, regardless of the TNF inhibitor employed or the dose provided.

PhRMA also requested that the CMS expand its examples of "substantial clinical improvements." That criterion came into play with Merck's application for bezlotoxumab, which is indicated to reduce recurrence of *Clostridium difficile* infection (CDI) in adult patients who are receiving antibacterial drug treatment for a diagnosis of CDI and who are at high risk for CDI recurrence. The big question here was whether the reported adverse event of cardiac failure with bezlotoxumab disqualified it as an "improvement." In the end, the CMS sided with Merck and agreed that because the drug represents a substantial clinical improvement over existing therapies, it would approve the extra payment given that the drug's label makes it clear that bezlotoxumab should be reserved for use when the benefit outweighs the risk for patients with a history of congestive heart failure.

The Medicare program's willingness to take a second look at initial decisions to deny add-on payments for drugs within DRGs is just another illustration of how the clearly delineated benefits of expensive new drugs can outweigh their costs. ■